REMARKS

Claims 1-58 and 62 have been canceled without prejudice. Claims 70-72 are withdrawn. Claims 59 and 64 are amended. Claims 59-69 and 37-77 are pending. Reconsideration is respectfully requested in light of the following remarks.

I. Election of Species

Applicants hereby elect the species of platinum compounds (Claim 69), hemangiomas (Claim 74), and ovarian tumor (Claim 76).

II. Claims Rejection – 35 USC § 112, Second Paragraph

Claim 64 stands rejected under 35 USC § 112, Second Paragraph. The Examiner states that claim 64 recites the limitation "2-50 mg/m^{2}" in claim 59. The Examiner states that there is insufficient antecedent basis for this limitation in the claim, as claim 59 specifically recites that the DNA methylation inhibitor is administered at a dose below 50 mg/m^2. The Examiner concludes that the upper limit of the administered dose cannot be 50 mg/m^2 as claimed in claim 64.

Applicants have amended claim 64 to limit the dose range to less than 50 mg/m^2. Applicant respectfully requests that the above objection be withdrawn.

III. Claims Rejection – 35 USC § 102(b)

Claims 59-62, 64-65, 67-69, and 75-76 stand rejected under 35 U.S.C. §102(b) as being anticipated by Lenzi, et al. (International Journal of Oncology (1995) 6:447-450). Applicants respectfully traverse the Examiner's rejection based on the following reasons.

Lenzi *et al.* fails to teach or suggest the claimed method of using a therapeutically effective amount of a DNA methylation inhibitor (e.g., decitabine) at a dose below 50 mg/m^2 per day for treating a patient having a tumor. Although Lenzi *et al.* disclose the combination of decitabine (or 2'-deoxy-5-azacytidine) at doses below 50 mg/m^2 in combination with cisplantin, the authors disclose on page 449, column 1, that no objective responses were seen in patients treated under the dosage conditions employed. In a second study in which the authors increased the dose of the DNA methylation inhibitor to 75 mg/m^2, the authors characterized the response rate at "poor" such that it

did not justify enrollment of additional patients (page 450, column 2). Thus, in view of amended claim 59, which recites the limitation of a "therapeutically effective amount", Lenzi *et al.* does not anticipate independent claim 59 nor any of the pending dependent claims. Accordingly, Applicants respectfully request that the above objection be withdrawn.

IV. Claims Rejection – 35 USC § 102(a)

Claims 59-62, 64-65, 67-69, and 75-76 stand rejected under 35 U.S.C. §102(a) as being anticipated by Plumb, *et al.* (Cancer Research (2000) 60:6039-6044). Applicants respectfully traverse the Examiner's rejection based on the following reasons.

Plumb *et al.* expressly states on page 6041, column 1, that "DAC treatment alone had no effect on tumor growth." Thus, Plum *et al.* does not anticipate independent claim 59 that claims the use of a therapeutically-effective amount of a DNA demethylation inhibitor, and the dependent claims 60-66, and 73-77.

Independent claim 59 also specifies intravenously or subcutaneously administering the therapeutically effective amount of a DNA methylation inhibitor to patient having a tumor. Plumb *et al.* teaches the administration of DAC by an intaperitoneal route of administration. Applicants respectfully disagree that the Office's definition of "subcutaneously" encompasses "intraperitoneal". Per MPEP 211.01, "the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification.... [T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d1321 (Fed. Cir. 2005)." Examiner correctly points out that Applicants have not defined "subcutaneously" in the specification. Hence, the term must be given its ordinary meaning as the term would be used by a person of ordinary skill in the art. Applicants submit that "subcutaneously", when used in the art of administration of therapeutic agents, would mean administration to the layers just under the skin, but would not include administration to the deep tissues or vasculature. Applicants refer Examiner to page 8 of the specification, wherein various routes of administration of the compounds of the present invention are listed; i.e.,

intravenously, subcutaneously, intraperitoneally...or intrathecally. Thus, if Applicants had intended to use subcutaneously to encompass intravenously or intraperitoneally in a fashion inconsistent with its ordinary meaning, the specification would not have included these terms in a disjunctive fashion. Accordingly, Applicants maintain that Plumb *et al.* fails to disclose administration of decitabine intravenously or subcutaneously and thus fails to anticipate the claimed invention under 35 U.S.C. §102(a). Withdrawal of these grounds of rejection is therefore respectfully requested.

V. Claims Rejection – 35 USC § 103

Claims 59-64, 66, and 73-76 stand rejected under 35 U.S.C. §103(a) as being unpatentable over WO/9901118 in further view of Lenzi et al.

As acknowledged by the Examiner, WO/9901118 does not specifically teach the dosage of decitabine is at a dose below 50 mg/m^2 per day. On the other hand, as discussed above, Lenzi *et al.* fails to teach or suggest the claimed method of using a therapeutically effective amount of a DNA methylation inhibitor (e.g., decitabine) at a dose below 50 mg/m^2 per day for treating a patient having a tumor. Thus, the cited references, each alone or in combination, fail to teach all elements of the claims. A prima facie case of obviousness has not been established under 35 U.S.C. §103(a). Withdrawal of these grounds of rejection is therefore respectfully requested.

VI. Non-Statutory Obviousness-Type Double Patenting

Claims 59-65, 67-69 and 75-76 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7-11 of U.S. Patent No. 6,613,753.

Applicants respectfully disagree with the Examiner's grounds for rejection. Yet, solely in an effort to further prosecution, and without prejudice, Applicants herein submit a Terminal Disclaimer for any term extending beyond the term of U.S. patent No. 6,630,329. This submission is made to put the pending claims in condition for allowance. In filing the Disclaimer, Applicant specifically reserves the right to address any double patenting issues in the future, whether or not mentioned in this Response, should the need arise. Applicant makes particular note of MPEP 804.02 II and established case law findings of the Federal Circuit, in *Quad Environmental Technologies v. Union*

Sanitary District, 946, F. 2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991), that the filing of a Terminal Disclaimer to obviate a rejection based on a non-statutory double patenting is not an admission of the propriety of the rejection. The filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection.

The Examiner also provisionally rejected claims 59-65, 67-69 and 75-76 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 14-17 and 19 of copending Application No. 10/867,621.

Pursuant to MPEP 804 I.B, if the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. Applicants submit that all of the other issues raised by the Examiner are properly addressed and the claims are patentable in view of the cited the references, Applicants respectfully request the Examiner to withdraw the provisional rejection on the ground of nonstatutory obviousness-type double patenting and allow issuance of the claims.

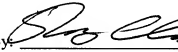
CONCLUSION

In light of the remarks set forth above, Applicants believe that they are entitled to a letters patent. Applicants respectfully solicit the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

The Commissioner is authorized to charge any underpayment or credit any overpayment to Deposit account No. 23-2415 (Attorney Docket No. 12636-330) for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: September 19, 2006

By 

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